

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 23

REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 10-14, 16 and 17 have been withdrawn from consideration by the Examiner. Claims 1-5, 7-9 and 15 have been rejected. Claims 1, 14 and 15 have been amended. Claims 10-13 and 16-17 have been canceled without prejudice. New claims 18 through 22 have been added. Support for these amendments is provided in the specification at page 14 through 16, page 32 through 33 and Example 1. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed October 2, 2003. Thus, the Examiner has withdrawn from consideration claims 6, 10-14, 16 and 17 and nucleic acid sequences other than SEQ ID NO:98 or 99 encoding SEQ ID 224. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 10-13, 16 and 17. Further, Applicants have amended the claims to be drawn to the elected sequence SEQ ID NO:98 or 99 encoding SEQ ID NO:224. In light of the Examiner's

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 24

acknowledgment that process claims that depend from or otherwise include all the limitations of the patentable product will be entered upon allowance of the product claim, Applicants have amended claim 14 to be drawn to claim 1 only and have indicated claim 6 to be withdrawn, not canceled. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Correction of Priority Claim

The specification has been amended at page 1, lines 4-6, to correct a typographical error in the serial number of the provisional application of which the instant application claims priority. In accordance with the executed Declaration, the claim of priority has been corrected to refer to U.S. Provisional Application Serial No. 60/243,802.

III. Objection to Disclosure

The Examiner has objected to the specification because of the following informalities.

Specifically, the Examiner suggests that the trademarks "megaBACE" at page 35, line 9, "Green-5-UTP" at page 36, line 12, "FastTag" at page 37, line 10, "pDisplay" at page 51, line 17, "Retropack" and EcoPack2-293" at page 53, line 13, "ExpressSF",

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 25

at page 58, line 25, "Calphos" at page 60, line 28 and "Effectene" at page 61, line 2, should be capitalized and accompanied by the generic terminology.

The Examiner also suggests that a blank appears at page 48, line 26 and page 75, line 16 in the phrase "yeast _mating system".

The disclosure has also been objected to for inclusion of embedded hyperlinks.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to capitalize the identified trademarks, correct the inadvertent typographical error in the phrase "yeast _-mating system" to state "--yeast α -mating system", a well known system in the art, as well as other typographical errors noted upon review of the specification and to inactivate any hyperlinks or other forms of browser executable code. Generic terminology was already included by the identified trademarks in the specification and thus is not required.

No new matter has been added by these amendment. Withdrawal of this objection is respectfully requested in light of these amendments.

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 26

IV. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph as the Examiner suggests that the claimed invention lacks patentable utility. Specifically, the Examiner suggests that none of the tables between pages 117 and 140 show a nexus between the presence or expression of SEQ ID NO:98 or 99 and breast cancer.

Applicants respectfully traverse this rejection.

Contrary to the Examiner's suggestion, SEQ ID NO:98 and SEQ ID NO:99 are identified as CLASP2 markers for breast cancer in Example 1 beginning at page 116 of the application. As made clear in the specification in Example 1, to qualify as a CLASP 2 candidate, a gene must exhibit detectable expression in tumor tissues and undetectable expression in libraries from normal individuals and libraries from normal tissue obtained from diseased patients and the gene must exhibit further specificity for the tumor tissues of interest. As made clear throughout the rest of the specification the tumor tissue of interest is breast cancer tissue. Accordingly, the Examiner's basis for this rejection for lack of utility of claims 1-5, 7, 8, 15 because a

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 27

nexus between the presence or expression of SEQ ID NO:98 and 99 and breast cancer is not disclosed is flawed.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:98 and 99 as having detectable expression specific for breast cancer tissue constitutes a pharmacological activity relevant to the asserted use as a diagnostic for breast cancer, thus satisfying the utility requirement with respect to these nucleic acid molecules.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the recitation of "a nucleic acid molecule that selectively hybridizes to the nucleic acid molecules of (a) or (b)" and "a

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 28

nucleic acid molecule having at least 60% identity to the nucleic acid molecule of (a) or (b)" encompasses a large genus of nucleic acid species not adequately described or disclosed.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that structural features that could distinguish compounds in the genus from others are missing from the disclosure and that no common structural attributes identify the members of the genus. All claimed nucleic acid sequence are distinguished based upon their common structural similarities to reference sequences explicitly disclosed in the instant specification.

Further, in an earnest effort to clarify structural limitations of the claimed nucleic acid sequences, claim 1, part (c) has been amended to set forth specific conditions of stringent hybridization as set forth in pages 14-16 used to identify the claimed sequence. Claim 1(d) has also been amended in accordance with teachings at page 32-33 to state that the nucleic acid sequence has 95% sequence identity to a nucleic acid sequence encoding SEQ ID NO:224 or a nucleic acid sequence comprising SEQ ID NO: 98 or 99. Further, Applicants have amended the claims to include the functional limitation that the

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 29

nucleic acid sequence is detectably expressed in breast cancer tissue in accordance with teachings of Example 1.

Contrary to the Examiner's suggestion, detailed methodologies for ascertaining sequences which meet the structural limitations of the instant amended claims are set forth in the specification at pages 13-16 and Example 1. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequences of SEQ ID NO:98 and 99 and their expression in breast cancer tissues, applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence as well as the amino acid sequence encoded thereby. The instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 30

VI. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7-9, and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Examiner regards as the invention.

Specifically, the Examiner suggests that the claims are vague and indefinite for claiming more than was elected.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the elected SEQ ID NO:98 or 99.

Further, the Examiner suggests that recitation of "selectively hybridizes" in claim 1 is vague, indefinite and incomplete because the term is a relative term one and no frame of reference is given.

Applicants respectfully disagree since what is meant by "selectively hybridizes" is described in detail in the specification at page 14. However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete this phrase and to clarify that the nucleic acid molecule hybridizes under defined stringent conditions in

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 31

accordance with teachings at page 14-16.

In addition, the Examiner suggest that claim 15 is vague and indefinite because the "means" for determining the presence of the nucleic acid as required by the kit is not clearly defined in the specification or claims.

Applicants respectfully disagree.

Exemplary means contemplated for determining the presence of a nucleic acid sequence are described in the patent application at pages 95-96.

MPEP § 2173 is quite clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. The content of the application in this case makes clear what is meant by stringent hybridization conditions and sets forth various means for detecting a nucleic acid in accordance with the claimed kits, thus meeting the requirements of 35 U.S.C. § 112, second paragraph. Further clarification in the claims is not required.

Withdrawal of these rejections under 35 U.S.C. § 112, second

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 32

paragraph is respectfully requested in light of the above remarks and the amendments to the claims.

VII. Rejection of Claims 1-5 under 35 U.S.C. § 102(b)

Claims 1-5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Stone et al. (Genbank Accession No. AC004168 submitted March 19, 1999). The Examiner suggests that Stone et al. discloses a nucleic acid sequence capable of hybridizing with the sequence of SEQ ID NO:99 said nucleic acid sequence having 90.8% similarity with the sequence of SEQ ID NO:99.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from the genomic sequence taught by Stone et al., Applicants have amended the claims to clarify that the nucleic acid hybridizes under defined stringent conditions or shares at least 95% identity with the sequence of SEQ ID NO:98 or 99 or the sequence encoding SEQ ID NO:224.

Stone et al. does not teach a nucleic acid molecule meeting all the limitations of these claims. Thus, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 33

VIII. Rejection of Claims 1-5 under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e)

Claims 1-5 have been rejected under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e) as being anticipated by Birren et al. (GenBank Accession No. AC012663, submitted November 2, 1999). The Examiner suggests that Birren et al. discloses a nucleic acid sequence capable of hybridizing with the sequence of SEQ ID NO:98, said nucleic acid sequence having 71% similarity with the sequence of SEQ ID NO:98.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from the genomic sequence taught by Birren et al., Applicants have amended the claims to clarify that the nucleic acid hybridizes under defined stringent conditions or shares at least 95% identity with the sequence of SEQ ID NO:98 or 99 or the sequence encoding SEQ ID NO:224.

Birren et al. does not teach a nucleic acid molecule meeting all the limitations of these claims. Thus, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

Attorney Docket No.: DEX-0249
Inventors: Sun et al.
Serial No.: 10/082,830
Filing Date: October 29, 2001
Page 34

IX. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Reg. No. 38,350

Date: June 8, 2004

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515